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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/377,866	08/20/99	KOZACHUK	W 7381.111

HM12/0105

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EXAMINER	
AULAKH, C	
ART UNIT	**PAPER NUMBER**
1612	4

DATE MAILED: 01/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/377,866	Kozachuk, W.E.
Examiner	**Group Art Unit**
Charanjit Aulakh	1612

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4-6 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 30

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. According to a preliminary amendment (paper no. 5), filed on Aug. 20, 1999, the applicants have canceled claims 1-3 and 7-8.

2. Claims 4-6 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glycine type NMDA receptor antagonist, felbamate, does not reasonably provide enablement for all other glycine type NMDA receptor antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case,

the specification is not enabling based on atleast four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

The instant claims are directed to administration of the glycine type NMDA receptor antagonists in vivo to patients and therefore, have to cross blood-brain barrier in order to produce their effect in the central nervous system. The specification does not teach that all available and future (to be developed) glycine type NMDA receptor antagonists will cross blood-brain barrier and therefore, will have utility for the intended purpose. In absence of such teachings, guidance and working examples, it would require undue experimentation to demonstrate the efectiveness of all glycine type NMDA receptor antagonists for the intended purpose.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 4-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sofia (U.S. Patent No. 5,055,489).

Sofia discloses a method for the treatment and prevention of hypoxic damage (neuroprotection) following a stroke or other cerebral ischemic events in humans or other warm-blooded animal patients by glycine type NMDA receptor antagonist, felbamate. Claim 1 of Sofia clearly anticipates the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell (Brain Research).

Newell discloses protection against ischemia-induced neuronal damage in hippocampal slice cultures by the glycine site NMDA receptor antagonist, Acea 1021. Newell does not teach adminstering Acea 1021 to humans for providing neuroprotection suffering cerebral ischemic insults. However, it would have been obvious to one skilled in the art to use glycine site NMDA receptor antagonists such as Acea 1021 for providing neuroprotection in patients suffering cerebral ischemic insults since Newell teaches that Acea 1021 may prove to be a clinically useful compound for providing neuroprotection in patients suffering cerebral ischemic insults due to its ability to cross the blood-brain barrier and apparent lack of behavioral side effects (see last paragraph on page 42).

8. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leeson (J. Medicinal Chem. Vol. 37, 1994, cited on applicant's form 1449).

Leeson discloses structure-activity relationships and therapeutic potential of the glycine site NMDA receptor antagonists. On page 4060, Leeson teaches that glycine site NMDA receptor

antagonists can protect against neuronal damage in animal models of cerebral ischemia, stroke etc. Leeson does not teach administering glycine site NMDA receptor antagonists to humans for neuroprotection. However, it would have been obvious to one skilled in the art to use the glycine site NMDA receptor antagonists for providing neuroprotection in patients suffering ischemic insults based on in vivo efficacy in the animal models as taught by Leeson.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703) 308-0204. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

C. S. Aulakh

CHARANJIT S. AULAKH

ASSISTANT EXAMINER